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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/806,828	Confirmation No. 4223
Applicant	:	Svava Maria Atladottir et al.	
Filed	:	March 22, 2004	
Art Unit	:	3731	
Examiner	:	Elizabeth Houston	
Docket No.	:	ACS.64880 (G2625USP3)	
Customer No.	:	68,919	June 4, 2010

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on March 5, 2010 in response to the Final Office Action of November 6, 2009. A request for a one month extension of time along with the requisite fee is being submitted herewith.

INTRODUCTION

The present invention relates to stents, and more particularly, to a self-expanding stent for treating a bifurcated vessel. The stent is configured to be positioned in a main vessel and self-expand into a branch vessel.

The present application, U.S. Serial No. 10/806,828, was filed on March 22, 2004 and is a continuation-in-part of an application filed May 17, 2001.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors SVAVA MARIA ATLADOTTIR, DAVID CHI, NAZANINE MATIN, SANTOSH PRBHU, SHAWN CHIN QUEE AND HANS F. VAENCIA to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment which was recorded by the U.S. Patent Office on March 22, 2004, beginning at Reel 015153, Frame 0137.

II. RELATED APPEALS AND INTERFERENCES

None

III. STATUS OF CLAIMS

The present application was originally filed with claims 1-42. Claims 16-37 and 39 were subsequently canceled pursuant to a Restriction Requirement. Claims

1-15, 38 and 40-42 are currently pending, are under final rejection and are being appealed herewith.

A clean copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

A response after the Final Office Action was filed on February 6, 2010. No claims were amended. In the Advisory Action of February 22, 2010, it was indicated that the request for reconsideration had been considered but did not place the application in condition for allowance.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 1-15, 38 and 40-42 are directed to a stent configuration.

Independent Claim 1:

Independent claim 1 is supported in the specification and drawings as follows:

1. A self-expanding stent for treating a bifurcated vessel having a main vessel and a side branch vessel (page 5, para. [0016], lines 1-4), comprising:

a cylindrical body having a central longitudinal axis (page 27, para. [000149], lines 3-7; Fig. 6A, #21), wherein such cylindrical body is defined by a plurality of rings spaced along such axis and wherein each ring is centered about such axis (page 27, para. [000149], lines 7-8; Fig. 7A, #30), adjacent rings being connected by links (page 27, para. [000149], lines 10-13; Fig. 7A, #31), and the cylindrical body having an unexpanded state (Fig. 6B) and an expanded state (Fig. 40);

the cylindrical body having a proximal section, a distal section, and a central section, each such section being defined by selected rings of said plurality of rings (page 28, para. [000150]; Fig. 7C, #26, #28, #29);

a number of first peaks in each of the rings of the central section differing from a number of first peaks in each of the rings of the proximal section and the distal section to thereby provide additional material for apposing a side branch vessel (page 28, para. [000150] - para. [000151], line 6; Fig. 6C, Fig. 40); and

the first peaks of the rings of the central section being configured to flare radially outwardly into an opening to the side branch vessel contacting the luminal wall of the side branch vessel and into at least a portion of the side branch vessel (page 28, para. [000151], lines 5-6; Fig. 40);

wherein the cylindrical body self-expands from the unexpanded state to the expanded state (page 65, para. [000226], lines 1-5).

Independent claim 38:

Independent claim 38 is supported in the specification and drawings as follows:

38. A stent for treating a bifurcated vessel having a main vessel and a side branch vessel (page 5, para. [00016], lines 1-4), comprising:

a cylindrical body (page 27, para. [000149], lines 3-7; Fig. 68, #21) including a superelastic alloy (page 65, para. [000226], line 2) and having a central longitudinal axis, wherein such cylindrical body is defined by a plurality of rings that are spaced along said axis and wherein each ring is centered about such axis, adjacent rings being connected by links (page 27, para. [000149], lines 10-13; Fig. 7A, #31), and the cylindrical body having an unexpanded state (Fig. 6B) and an expanded state (Fig. 40); and

the cylindrical body having a proximal section, a distal section, and a central section (page 23, para. [000150]; Fig. 7C, #26, #28, #29), each such section being formed

by selected rings of said plurality of rings, wherein an opening is defined between said central section and said distal section (page 29, para. [000153], lines 5-9; Fig. 6A, #40), wherein the central section has a number of first peaks in each ring differing from a number of first peaks in each ring of the proximal section and the distal section to thereby provide additional material for apposing a side branch vessel (page 28, para. [000150] – para. [000151], line 6; Fig. 6C, Fig. 40).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the final Office Action mailed November 6, 2009, the claims were rejected as follows:

GROUND I

Claims 1-8 were rejected under 35 U.S.C. § 102(b) as anticipated by Vardi (WO99/36002)

GROUND II

Claims 9, 10, 15, 38 and 40-42 were rejected under 35 U.S.C. § 103(a) as obvious over Vardi (WO99/36002) in view of Roubin (USPN 5,827,321).

GROUND III

Claims 11-14 were rejected under 35 U.S.C. § 103(a) as obvious over Vardi (WO99/36002) in view of Roubin (USPN 5,827,321) and further in view of Guruwaiya (USPN 6,251,136).

VII. ARGUMENT

GROUND I

Independent claim 1 specifies a self-expanding stent configuration wherein such stent is defined by a plurality of rings that are each centered about the stent's central longitudinal axis and wherein the stent's central section has additional peaks that flare radially outward into the branch vessel to appose the branch vessel wall. Additionally, the claim specifically requires the stent to "self-expand from the unexpanded state to the expanded state." The Examiner relies on the Vardi reference, and more specifically, on Fig. 10 of such reference to support the anticipation rejection. While the Examiner asserts that device shown and described in the cited reference self-expands from its unexpanded state to an expanded state, this is patently incorrect.

Throughout the Vardi reference, the stent configurations that are described therein are referred to as being "expandable" rather than "self-expanding," wherein such descriptors are commonly used in the art to refer to stents that require the application of an expansive force to undergo expansion and stents that expand without the application of an expansive force respectively. The fact that the cited reference is exclusively directed to stents that are "expandable," rather than "self-expanding" is further fully supported in the cited reference by virtue of the use of inflatable balloons to expand the stents as is clearly shown in the Figures (e.g. Figs. 4-8 and 13B-13G) and as is articulated in the written description of the stents' deployment. Moreover, there is no description or suggestion as to how the subject stents could assume the various configurations during their deployment without the use of inflatable balloons.

The distinction between a stent that does not require the application of an expansive force to deploy and one that does is critical with regard to the present

invention as it is being claimed because while the latter cannot "self-expand from the unexpanded state to the expanded state," independent 1 specifically requires the stent to do so. Moreover, while a self-expanding stent can be "configured **to flare** radially outwardly," a stent that requires the application of an expansive force cannot be configured to flare radially outward but rather, would necessarily have to be "configured **to be flared** radially outwardly into an opening." Independent claim 1 unequivocally calls for the stent to be configured to flare radially outwardly. As such, independent claim 1 and claims 2-8 that depend therefrom clearly avoid anticipation.

Anticipation is further avoided in view of the fact that the claims specify that it is the "first" peaks of the central section that flare outwardly into the side branch vessel wherein "first" peaks are also specified as being present in the proximal and distal sections. In view of the fact that the peaks that are shown in the cited reference that are to be flared into the side branch vessel are not of the same size, shape nor orientation as those found in the stent's end sections, they cannot reasonably also be characterized as comprising, nor be counted as, "first" peaks. Otherwise, the attached adjective would have lost all meaning and significance. In view of the fact that the cited reference does not suggest a structure in which the number of "first" peaks in the central section differs from the number of "first" peaks in the end sections, and wherein the "first" peaks of central section flare radially outwardly into a side branch vessel, it is respectfully submitted that anticipation is further avoided.

GROUND II

The Examiner rejects those claims that require the stent to be formed of a material that enables the stent to self-expand, such as a self-expanding alloy (claim

9), Nitinol (claim 10), a superelastic material (claim 15) and a superelastic alloy (claims 38 and 40-42) relying on the Vardi reference for the teaching of a stent structure and relying on the Roubin et al reference for the use of various self-expanding materials. However, there is absolutely no suggestion that the structure taught by Vardi would be capable of flaring radially outwardly into an opening to the side branch vessel as is required in all claims that depend from independent claim 1, i.e. claims 9, 10 and 15, upon expansion of the stent. There is nothing to suggest that the **expansion** of the stent would cause the "plurality of elements which are attached to the peripheral edge of the side opening 16" (page 11, lines 19-20) in Fig. 9 or the "plurality of loops" 109 shown in Fig. 10 to flare into the side branch vessel. The expansion of the stent and the flaring of the tabs require two different mechanisms that are handled as separate steps in the cited reference, each of which is accomplished by the extension and inflation of a different balloon. There is no suggestion or teachings as to how such a complex expansion could be achieved simply with the use of a self-expanding material. The present invention on the other hand provides a elegant solution to such problem with simply the incorporation of additional "first" peaks in the rings of the central section that allow the central section to expand to a greater diameter and thereby flare into the side branch vessel. It is respectfully submitted that such solution is not in any way suggested by the cited references and that obviousness is thereby effectively avoided.

Further with regard to the rejection of claims 9, 10 and 15 as well as claims 38 and 40-42 as obvious, it is to be noted that the cited references do not suggest or teach that it is the additional number of "first" peaks in the central section that provide material for apposing a side branch vessel. The primary reference clearly shows a very different approach wherein a structure with substantially greater

complexity is relied upon to provide material for extending into a side branch vessel. Notwithstanding the fact that there is no teaching as to how the use of a self-expanding material could cause a part of the structure shown in the primary reference to flare into the side branch vessel, the peaks of such part of the structure are completely different than any of the peaks found in the end sections of the stent. As was argued above, the present invention provides a simple structure that is capable of apposing a side branch vessel and is capable of doing so simply by undergoing self-expansion. As such, it is respectfully submitted that obviousness is effectively avoided.

GROUND III

The Examiner rejects claims 11-14 which require the stent to be self-expanding by relying on the Vardi reference for the teaching of a stent structure and relying on the Roubin et al reference for the use of various self-expanding materials. However, there is absolutely no suggestion that the structure taught by Vardi would be capable of flaring radially outwardly into an opening to the side branch vessel as is required in all claims that depend from independent claim 1, i.e. claims 9, 10 and 15, upon expansion of the stent. There is nothing to suggest that the **expansion** of the stent would cause the "plurality of elements which are attached to the peripheral edge of the side opening 16" (page 11, lines 19-20) in Fig. 9 or the "plurality of loops" 109 shown in Fig. 10 to flare into the side branch vessel. The expansion of the stent and the flaring of the tabs require two different mechanisms that are handled as separate steps in the cited reference, each of which is accomplished by the extension and inflation of a different balloon. There is no suggestion or teachings as to how such a complex expansion could be achieved simply with the use of a self-expanding material. The present invention on the other hand provides a elegant solution to such problem with simply the

incorporation of additional "first" peaks in the rings of the central section that allow the central section to expand to a greater diameter and thereby flare into the side branch vessel. It is respectfully submitted that such solution is not in any way suggested by the cited references and that obviousness is thereby effectively avoided.

Further with regard to the rejection of claims 11-14 as obvious, it is to be noted that the cited references do not suggest or teach that it is the additional number of "first" peaks in the central section that flare into the side branch vessel and provide material for apposing the side branch vessel. The primary reference clearly shows a very different approach wherein a structure with substantially greater complexity is relied upon to provide material for extending into a side branch vessel. Notwithstanding the fact that there is no teaching as to how the use of a self-expanding material could cause a part of the structure shown in the primary reference to flare into the side branch vessel, the peaks of such part of the structure are completely different than any of the peaks found in the end sections of the stent. The Guruwaiya reference does not in any way overcome the shortcomings of the other two references. As was argued above, the present invention provides a simple structure that is capable of apposing a side branch vessel and is capable of doing so simply by undergoing self-expansion. As such, it is respectfully submitted that obviousness is effectively avoided.

VIII. CLAIM APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

XI. CONCLUSION

As argued above, it is respectfully submitted that the present invention as claimed is not obvious over the cited references. Reversal of the rejections of claims 1-15, 38 and 40-42 is therefore respectfully requested.

Respectfully submitted,

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/Gunther O. Hanke/
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EXHIBIT 1 - CLAIMS

1. A self-expanding stent for treating a bifurcated vessel having a main vessel and a side branch vessel, comprising:

a cylindrical body having a central longitudinal axis, wherein such cylindrical body is defined by a plurality of rings spaced along such axis and wherein each ring is centered about such axis, adjacent rings being connected by links, and the cylindrical body having an unexpanded state and an expanded state;

the cylindrical body having a proximal section, a distal section, and a central section, each such section being defined by selected rings of said plurality of rings;

a number of first peaks in each of the rings of the central section differing from a number of first peaks in each of the rings of the proximal section and the distal section to thereby provide additional material for apposing a side branch vessel; and

the first peaks of the rings of the central section being configured to flare radially outwardly into an opening to the side branch vessel contacting the luminal wall of the side branch vessel and into at least a portion of the side branch vessel;

wherein the cylindrical body self-expands from the unexpanded state to the expanded state.

2. The stent of claim 1, wherein the rings of the proximal section have between four and twelve first peaks, the rings of the distal section have between four and twelve first peaks, and the rings of the central section have between five and fifteen first peaks.

3. The stent of claim 1, wherein the rings of the proximal section have seven first peaks, the rings of the distal section have six first peaks, and the rings of the central section have eight first peaks.

4. The stent of claim 1, wherein the number of first peaks in the ring(s) of the central section is greater than the number of first peaks in any of the rings in either the proximal section or the distal section.

5. The stent of claim 1, wherein the rings are connected by at least one links between adjacent rings.

6. The stent of claim 1, wherein the tubular body has a distal opening, a proximal opening, and a central opening.

7. The stent of claim 6, wherein the distal opening and the proximal opening are aligned along the stent longitudinal axis.

8. The stent of claim 7, wherein the central opening is radially offset relative to the alignment of the distal opening and the proximal opening.

9. The stent of claim 1, wherein the stent is formed from a self-expanding alloy.

10. The stent of claim 9, wherein the self-expanding alloy is nitinol.

11. The stent of claim 1, wherein the stent is coated with at least one layer of a drug.

12. The stent of claim 1, wherein the stent is coated with at least one layer of a therapeutic agent.

13. The stent of claim 1, wherein at least a portion of the stent is coated with at least one layer of a therapeutic agent.

14. The stent of claim 1, wherein at least a portion of the stent is coated with a primer material which adheres to the stent, the primer material being coated with at least one layer of a therapeutic agent or drug.

15. The stent of claim 1, wherein the stent is formed of a superelastic material that enables the central section first peaks to self-expand and flare radially outward to contact the luminal wall of the side branch vessel, and wherein the central section includes a diameter that is larger than a diameter of the proximal section.

38. A stent for treating a bifurcated vessel having a main vessel and a side branch vessel, comprising:

a cylindrical body including a superelastic alloy and having a central longitudinal axis, wherein such cylindrical body is defined by a plurality of rings that are spaced along said axis and wherein each ring is centered about such axis, adjacent rings being connected by links, and the cylindrical body having an unexpanded state and an expanded state; and

the cylindrical body having a proximal section, a distal section, and a central section, each such section being formed by selected rings of said plurality of rings, wherein an opening is defined between said central section and said distal section , wherein the central section has a number of first peaks in each ring differing from a number of first peaks in each ring of the proximal section and the distal section to thereby provide additional material for apposing a side branch vessel.

40. The stent of claim 38, wherein the central section first peaks being configured to flare radially outwardly into an opening to the side branch vessel and into at least a portion of the side branch vessel.

41. The stent of claim 38, wherein the cylindrical body self-expands from the unexpanded state to the expanded state.

42. The stent of claim 38, wherein the cylindrical body is formed from a single hypotube.